

K130020



### **510(k) Summary**

Prepared September 30, 2013

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

#### **Submitter's Name and Address**

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OCT 01 2013

#### **Device Name**

Trade Name: Access Total  $\beta$ hCG (5<sup>th</sup> IS) Assay and Access Total  
 $\beta$ hCG (5<sup>th</sup> IS) Calibrators on the Access®  
Immunoassay Systems  
Common Name: Human chorionic gonadotropin  
Classification Name: Human chorionic gonadotropin (HCG) test system  
(21 CFR 862.1155)  
Secondary Calibrator (21CFR 862.1150)

#### **Predicate Device**

ADVIA Centaur Total hCG Assay (k925277)  
Manufactured by Siemens Healthcare Diagnostics, Inc.

**Device Description**

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay (standardized to WHO 5<sup>th</sup> International Standard), Access Total  $\beta$ hCG (5<sup>th</sup> IS) calibrators, and the Access Immunoassay analyzers comprise the Access Immunoassay System for the quantitative determination of total  $\beta$ hCG in human serum and plasma.

**Intended Use**

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the in vitro quantitative determination of total  $\beta$ hCG levels in human serum and plasma using the Access Immunoassay Systems. This assay is intended for use as an aid in the early detection of pregnancy.

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) Calibrators are intended to calibrate the Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay for the quantitative determination of total  $\beta$ hCG levels in human serum and plasma using the Access Immunoassay Systems.

### Comparison of Technological Characteristics

Parameter	Access Total $\beta$ hCG (5 <sup>th</sup> IS) Assay and Access Total $\beta$ hCG (5 <sup>th</sup> IS) Calibrators	Predicate ADVIA Centaur Total hCG
Intended use	<p>The Access Total <math>\beta</math>hCG (5<sup>th</sup> IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total <math>\beta</math>hCG levels in human serum and plasma using the Access Immunoassay Systems. This assay is intended for use as an aid in the early detection of pregnancy.</p> <p>The Access Total <math>\beta</math>hCG (5<sup>th</sup> IS) Calibrators are intended to calibrate the Access Total <math>\beta</math>hCG (5<sup>th</sup> IS) assay for the quantitative determination of total <math>\beta</math>hCG levels in human serum and plasma using the Access Immunoassay Systems</p>	For <i>in vitro</i> diagnostic use in the quantitative determination of human chorionic gonadotropin (hCG) in serum using the ADVIA Centaur and ADVIA Centaur XP systems. The results obtained from hCG specimens are used as an aid in the assessment of pregnancy status. The assay detects the intact hCG molecule and free beta-subunit of the hCG molecule
Analyte Measured	Total $\beta$ hCG (intact hCG and free beta-subunit)	Intact hCG and free beta-subunit hCG
Standardization	WHO 5 <sup>th</sup> International Reference Preparation, Chorionic Gonadotropin, NIBSC Coded 07/364	WHO 4 <sup>th</sup> International Reference Preparation, Chorionic Gonadotropin, NIBSC Coded 75/589
Technology	Sandwich immunoassay	Sandwich immunoassay
Format	Chemiluminescent	Chemiluminescent
Method	Automated	Automated
Calibration	Utilizes a stored calibration curve	Utilizes a stored calibration curve
Calibrator Levels	6 levels (0 mIU/mL, and approximately 6, 35, 195, 620 and 1350 mIU/mL)	2 levels (Low at approximately 7 mIU/mL and High at approximately 300 mIU/mL)
Calibrator Matrix	Bovine serum albumin	Equine serum
Calibration Curve Stability	28 days	28 days
Sample Type	Serum or plasma	Serum
Measuring Range	0.6 – 1350 mIU/mL (IU/L)	2.0 – 1000 mIU/mL (IU/L)

## Summary of Studies

**Method Comparison:** A comparison of 224 serum samples with hCG concentrations ranging from approximately 3.2 to 1095.9 mIU/mL were run on both the Access Total  $\beta$ hCG (5<sup>th</sup> IS) immunoassay and the predicate Siemens ADVIA Centaur Total hCG immunoassay. The results were compared using Passing-Bablok regression and Pearson correlation with the predicate on the x-axis. The observed linear fit had a slope = 1.04 with 95% confidence interval of 1.02 to 1.06, an intercept = 2.87 mIU/mL and a  $r = 0.99$ .

**Imprecision:** Serum and plasma samples within run imprecision ranged from 1.8 to 4.8 %CV, between run imprecision ranged from 0.9 to 6.0 %CV, and total imprecision ranged from 2.6 to 6.6 %CV at levels between 3.9 and 1350 mIU/mL. The assay exhibits total imprecision of less than 10% CV for concentrations greater than 3.9 mIU/mL and  $\leq 0.39$  SD at concentrations  $\leq 3.9$  mIU/mL.

**High-dose Hook Effect:** The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay demonstrated no high-dose hook to 1,000,000 mIU/mL in a serum sample.

**Linearity:** The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay has demonstrated to be linear across the range of the assay (0.6 to 1350 mIU/mL) in serum samples.

**Dilution Recovery:** The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay has been demonstrated to dilute recover across the range of the assay (0.6 to 1350 mIU/mL) in serum and plasma samples. Samples containing hCG concentrations from approximately 1150 mIU/mL to 270,000 mIU/mL can be diluted 200-fold and average recovery  $100 \pm 15\%$ .

**Limit of Blank (LoB):** The highest measurement result observed with no analyte present in a serum sample is  $\leq 0.5$  mIU/mL ( $n=156$ ).

**Limit of Detection (LoD):** The lowest concentration of analyte in a serum sample that can be detected with a stated probability (95%) is  $\leq 0.5$  mIU/mL.

**Limit of Quantitation (LoQ):** The lowest concentration of analyte in serum and plasma samples that can be quantitatively determined is  $\leq 0.6$  mIU/mL.

**Analytical Specificity:** There is no significant interference from total protein, bilirubin, hemoglobin, or triglycerides in serum samples. Additionally, substances similar in structure to hCG when added to a patient serum sample with an approximate hCG concentration of 2.9 mIU/mL showed no significant cross-reactivity.

**Isoform Recognition:** In serum samples, the Access Total  $\beta$ hCG 5<sup>th</sup> IS assay recognizes intact hCG, the  $\beta$  subunit of hCG, nicked intact hCG and nicked  $\beta$ hCG isoforms. The free  $\alpha$ -subunit and  $\beta$ -core fragment yield no detectable response.

**Expected Values:** Total  $\beta$ hCG concentrations were measured in human serum samples collected from apparently healthy non-pregnant females, which included pre-menopausal and post-menopausal women, using the Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay. Concentrations of total  $\beta$ hCG measured in 100% of samples were determined to be  $\leq 11.6$  mIU/mL (IU/L).

**Matrix Comparison:** A comparison of forty-two (42) matched sets of serum (gel and no gel) and plasma (lithium-heparin) samples with hCG concentrations ranging from approximately 0.5 to 1350 mIU/mL were compared using Passing-Bablok regression with serum (no gel) on the x-axis. The observed linear fit for serum vs. serum (gel) had an estimated slope = 0.99 with a confidence interval (CI) of 0.98 to 1.01, and an estimated intercept = -0.05 mIU/mL with a CI of -0.15 to 0.10 mIU/mL. The observed linear fit for serum vs. plasma had an estimated slope = 1.05 with a CI of 1.02 to 1.07, and an estimated intercept = -0.08 mIU/mL with a CI of -0.28 to 0.05 mIU/mL.

### **Conclusion:**

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) Assay and Access Total  $\beta$ hCG (5<sup>th</sup> IS) Calibrators, for use on the Access Immunoassay Systems, are substantially equivalent to the predicate device, Siemens ADVIA Total hCG assay (k925277) for the measurement of hCG and are safe and effective for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - W066-G609  
Silver Spring, MD 20993-0002

October 1, 2013

Beckman Coulter, Inc.  
c/o Geraldine L. Baglien  
1000 Lake Hazeltine Drive  
CHASKA MN 55318-1084

Re: K130020

Trade/Device Name: Access Total  $\beta$ hCG (5th IS) Assay  
Access Total  $\beta$ hCG (5th IS) Calibrators  
Regulation Number: 21 CFR 862.1155  
Regulation Name: Human chorionic gonadotropin (HCG) test system  
Regulatory Class: II  
Product Code: DHA, JIX  
Dated: September 17, 2013  
Received: September 18, 2013

Dear Ms. Baglien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Carol C. Benson -S** for

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K130020

Device Name: Access Total  $\beta$ hCG (5<sup>th</sup> IS) Assay and Access Total  $\beta$ hCG (5<sup>th</sup> IS) Calibrators on the Access® Immunoassay Systems.

### Indications for Use:

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total  $\beta$ hCG levels in human serum and plasma using the Access Immunoassay Systems. The assay is intended for use as an aid in the early detection of pregnancy.

The Access Total  $\beta$ hCG (5<sup>th</sup> IS) calibrators are intended to calibrate the Access Total  $\beta$ hCG (5<sup>th</sup> IS) assay for the quantitative determination of total  $\beta$ hCG levels in human serum and plasma using the Access Immunoassay Systems.

Prescription Use  X   
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use        
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S

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Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k)  k130020